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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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| In re Application of | : |
| Schadt | : |
| Serial No.: 10/552,064 | :Decision on Petition |
| Filed: 5 October 2005 | : |
| Attorney Docket No.: Merck-3067 | : |

This letter is in response to the Petition filed under 37 C.F.R. 1.181 filed on 26 September 2008 requesting withdrawal of the restriction requirement. The delay in acting upon this petition is regretted.

BACKGROUND

This application was filed under the provisions of 35 U.S.C. 371 and as such is subject to PCT Unity of Invention practice.

On 14 March 2007, the examiner mailed a restriction requirement in which the original 17 claims were divided into 111 groups. The examiner also required the election of a single species of Formula I. The examiner stated that the compound of formula I is taught by Baron et al and as such, does not make a contribution over the prior art.

On 3 April 2007, Applicants elected Group III, claims 1-7, 10, 14 and 17 and compound 8 of example 7 with the traversal that the Office has not established that it would be a burden to examine the full scope of the claimed invention. Group III is defined in the restriction requirement as the compounds of Formula I wherein variables X, R2, and R3/R4 are defined as C, C0-5-Furan and C0-5-Piperazine, respectively.

On 7 May 2007, the examiner considered the traversal and rejoined claims 8-13 and 15-17, directed to methods of making the compounds of Group III and the methods of using the

compounds of Group III with elected Group III. The examiner made the restriction requirement FINAL. Claims 1-17 were searched and examined on the merits, as follows:

Claims 11-13 and 16 were rejected under 35 U.S.C. 112, 2nd paragraph and 35 USC 101 as being directed to "use" claims.

Claims 1-17 were rejected under 35 U.S.C. 112 2nd paragraph for indefiniteness concerning values of R3 and R4.

Claims 1-2 and 11-14 were provisionally rejected under non-statutory obviousness type double patenting.

The examiner indicated that compounds I-703 that fall within the elected group are free of the prior art of record.

On 8 July 2007, applicants filed a response to the Office action, an amendment to the claims and a Terminal Disclaimer.

On 26 September 2007, the examiner rejected claims 1-13 and 15-22 under 35 USC 112, 1st paragraph for lack of enablement. Claims 1, 3, 6, 10 and 19 were rejected under 35 USC 102(b) as being anticipated by Bamaung et al. Claims 1, 4, 6-8, 10, 19 and 21 were rejected under 35 USC 102(b) as being anticipated by Beck et al. Claims 1, 4-7, 19 and 21 were rejected under 35 USC 103(a) as being unpatentable over Schiemann et al. Claim 19 and 21 were objected to for being substantial duplicates of claims 1 and 7, respectively. Claims 1-2 and 11-14 were provisionally rejected under non-statutory obviousness type double patenting. The Office action was made FINAL.

In an Interview Summary dated 19 October 2007, the examiner withdrew the finality of the Office action mailed 26 September 2008 in view of the new grounds of rejection.

On 26 February 2008, Applicants filed a response to the Office action, including an amendment to the claims.

On 9 July 2008, the examiner rejected claims 1-13, 15-18, 23 and 25-27 under 35 USC 112, 1st paragraph for lack of enablement. Claims 1, 7-13 and 15-24 were objected to for containing non-elected subject matter. The Office action was made FINAL.

On 26 September 2008, Applicants filed a response to the Office action and this petition.

DISCUSSION

The petition and file history have been carefully considered.

At the onset, it is noted that the Office action mailed 9 July 2008 is incomplete and inconsistent with regard to the treatment of the claims, and as such, was vacated on 9 January 2009.

Further, it is noted that the statement identifying an "improper Markush group" in the unity of invention determination mailed 14 March 2007 is incorrect. There is no established criteria for

what is a proper or an improper Markush group, nor does the Office have any means to object or reject a claim solely for containing an improper Markush group.

Moreover, it is noted that applicants elected Group III as defined in the restriction requirement as the compounds of Formula I wherein variables X, R2, and R3/R4 are defined as C, C0-5-Furan and C0-5-Piperazine, respectively. The examiner rejoined the methods of making or using with the elected product and then issued an Office action on the merits for Claims 1-17. This included an Office action on Claim 6.

6. (Previously Presented) A compound of formula I according to claim 1, in which X denotes N.

Claim 6 is defined by Group XI, the compounds of Formula I wherein variables X, R2, and R3/R4 are defined as N, C0-5-Furan and C0-5-Piperazine, respectively. Because Claim 6 has been examined on the merits, the restriction requirement set forth between Group III and XI is withdrawn.

Turning now to the merits of the petition, the petition argues that the examiner should follow the practice set forth in MPEP 803.02 for the restriction practice of MPEP 803.02 for Markush claims. This is not persuasive for the following reasons.

This application is a national stage filing of PCT/EP04/02453 and as such, is eligible for the restriction practice set forth in Chapter 10 of the International Preliminary Search and Examination Guidelines and Unity of Invention Practice set forth in MPEP Chapter 1800, particularly sections 1850 and 1893.03(d). Moreover, even if the guidance in MPEP 803.02 applied to this application, it is noted that the examiner is not required to extend the search and examination to a second or subsequent species until the elected species is in condition for allowance. At this time, not all claims directed to the elected species are in condition for allowance, so any request for extended examination is considered premature.

Next, the petition argues that 35 USC 121 does not give the Office authority to divide a single claim up into several applications. This is not persuasive because 37 CFR 1.475(e) permits the Office to restrict among inventions recited in the alternative of a single claim in an application filed under 35 USC 371. See 37 CFR 1.475(e).

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

Guidance on unity of invention for chemical compounds may be found in the International Search and Preliminary Examination Guidelines. Paragraph 10.17 states:

Rule 13.2 also governs the situation involving a single claim that defines alternatives (chemical or non-chemical), the so-called "Markush practice." In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical

features as defined in Rule 13.2, is considered met when the alternatives are of a similar nature.

(a) When the Markush grouping is for alternatives of chemical compounds, they are regarded as being of a similar nature where the following criteria are fulfilled:

(A) all alternatives have a common property or activity, and

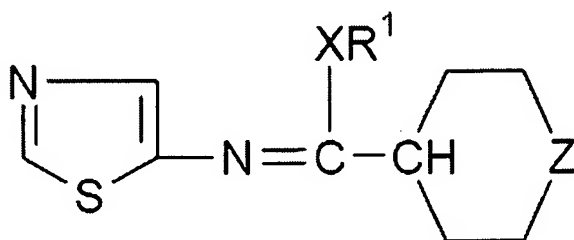
(B)(1) a common structure is present, that is, a significant structural element is shared by all of the alternatives, or

(B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

(b) In paragraph (a)(B)(1), above, the words “significant structural element is shared by all of the alternatives” refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The structural element may be a single component or a combination of individual components linked together....

The ISPE Guidelines provide several examples, including Example 20: Common Structure

Claim 1: A compound of the formula:

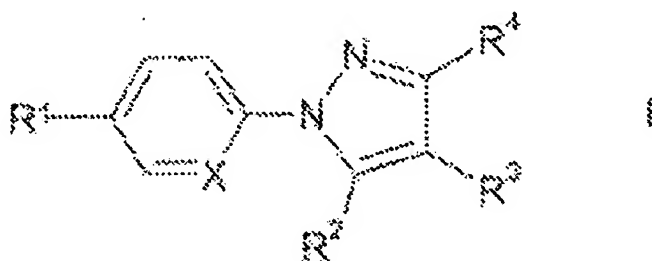


wherein R¹ is methyl or phenyl, X and Z are selected from oxygen (O) and sulfur (S).

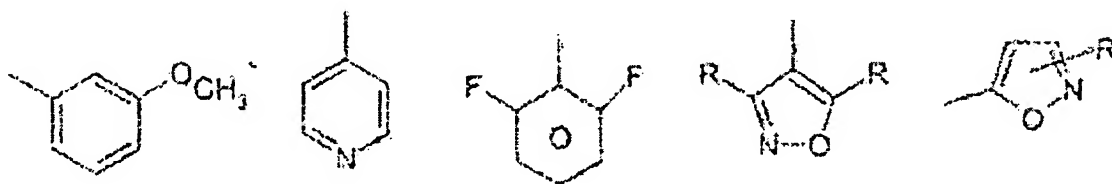
The compounds are useful as pharmaceuticals and contain the 1,3-thiazolyl substituent which provides greater penetrability of mammalian tissue which makes the compounds useful as relievers for headaches and as topical anti-inflammatory agents. All compounds share a common chemical structure, the thiazole ring and the six atom heterocyclic compound bound to an imino group, which occupy a large portion of their structure. Thus, since all the claimed compounds are alleged to possess the same use, unity would be present.

In Example 20, the core structure permits three variables which result in 8 possible compounds. The substituents for "X", "Z" and "R1" are all small in size in comparison to the overall core structure. Thus the common chemical structure of Example 20 occupies a large portion of the structure.

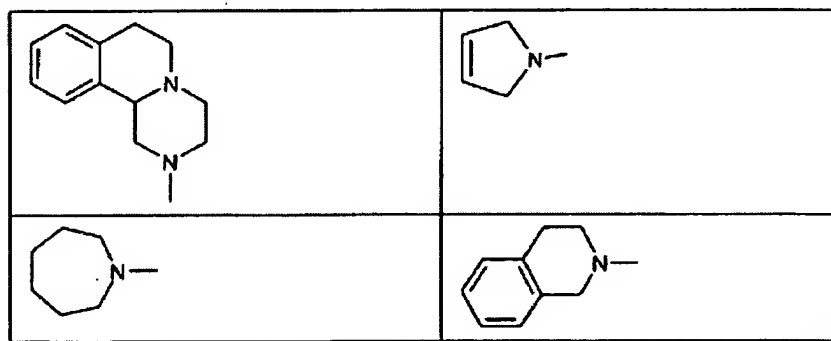
In contrast, to ISPE Guidelines Example 20, the claimed compound of Formula 1 has 5 variables described by two full pages of possible substituents. See Formula I:

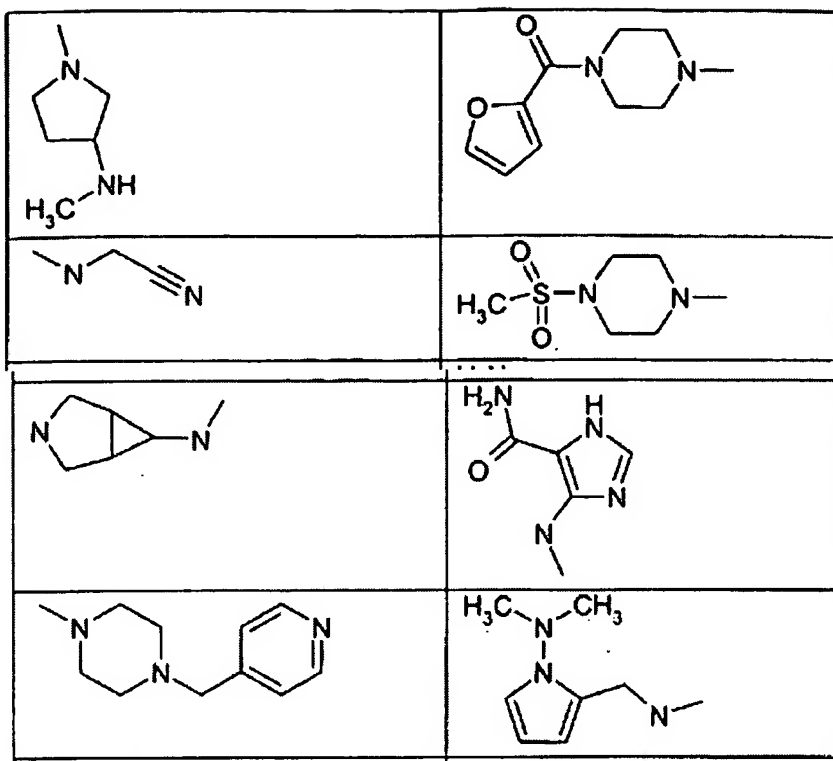


in which R2 may be, for example,



Pages 12-16 of the specification provide many options for the "Het" portion of R2, R3 and R4, including, for examples,





Thus, the possible side chains of the compounds encompassed by the claim vary in structure and in size. It is noted that structural variation permitted by the instant claims is far more complicated and extensive than just two page list of claim, as it recites nested variables, provisos and ranges of substituents described in generic terms. Given the possible variables for R3 and R4, 20 possibilities for R1, 12 possibilities for R2, and two possible meanings for X, there are at least 35 billion compounds encompassed by the scope of Formula I.

Moreover, a sample search query for the required core structure projected at least 38 million iterations, indicating that the required common core does not make a contribution over the prior art. For these reasons, the common structure of Formula I is not considered as a significant structural feature and the requirement to elect a particular combination of variables for R2 and R3/R4 for examination is maintained.

DECISION

The petition is **GRANTED-IN PART** for the reasons set forth above.

Because Claim 6 has been examined, the restriction requirement set forth between Group III and Group XI is withdrawn. The elected invention is defined as the compounds of Formula I wherein variables R2 and R3/R4 are defined as C0-5-Furan and C0-5-Piperazine, respectively, compositions comprising such and products of making and using such. The lack of unity determination amongst the compounds groups is otherwise maintained.

Should the shared technical become a contribution over the prior art the examiner should reconsider the lack of unity determination. Moreover, should all claims directed to the elected invention become in condition for allowance, the examiner should follow rejoinder practice set forth in MPEP 821.04.

The application will be forwarded to the examiner for consideration of the papers filed on 26 September 2008 and for action consistent with this decision.

Any request for reconsideration must be filed within two (2) months of the mailing date of this decision.

Should there be any questions about this decision, please contact Special Program Examiner Julie Burke, by letter addressed to Director, Technology Center 1600, at the address listed above, or by telephone at 571-272-1600 or by facsimile sent to the general Office facsimile number, 571-273-8300.

A handwritten signature in black ink, appearing to read 'Remy Yucel', with a long, sweeping horizontal line extending to the right.

Remy Yucel
Director, Technology Center 1600